



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

58300-25

Date of Issuance:

6/30/17

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

SteriCide

Name and Address of Registrant (include ZIP Code):

ConSeal International, Inc.
90 Kerry Place, Suite 2
Norwood, MA 02062

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Zeno Bain, Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

7/3/17

2. You are required to comply with the data requirements described in the DCI's identified below:
 - a. Ethaneperoxoic Acid GDCI-063201-1125
 - b. Hydrogen Peroxide GDCI-000595-1127

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 58300-25."
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 5/15/2017

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

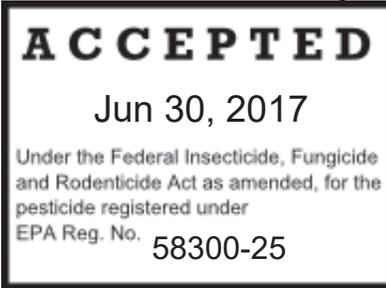
Enclosure: Approved Label

SteriCide

[RTU Sterilant

SteriCide is for use as a detergent cleaner, deodorizer, disinfectant, fungicide, and sporicide/sterilant on non-porous hard surfaces in commercial, hospital, and medical environments.]

ACTIVE INGREDIENTS:	
Hydrogen peroxide	6.14%
Peracetic acid	0.60%
OTHER INGREDIENTS	
Total.....	100.00%



DANGER
KEEP OUT OF REACH OF CHILDREN

[See [booklet] [side] [back] panel for additional Precautionary Statements [and First Aid]]

{First Aid statements will be placed on front panel, room permitting. If not a descriptor will be used.}

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or doctor for treatment advice.
IF SWALLOWED	Call a poison control center or doctor immediately after treatment for advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
Have the product container with you when calling a poison control center or going for treatment. You May also contact 1-800-222-1222 for emergency medial treatment information.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage. Harmful if swallowed. -Avoid contact with skin or on clothing. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco. Remove and wash contaminated clothing before reuses.

PHYSICAL AND CHEMICAL HAZARDS

Strong Oxidizing Agent. Corrosive. Never mix or use this product in combination with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office at the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Suitable for use on most hard, non-porous surfaces in commercial or health care sites including:

[Academic Facilities	Dental Facilities	Office Buildings
Airports	Farms	Recreational/Entertainment Facilities
Animal Hospitals and Veterinary Facilities	Funeral Homes	Retail and Wholesale Establishments
Animal Life Science Laboratories	Hospitals	Salons
Animal Shelters/Care Facilities	Health Care Facilities	Spas
Autopsy Facilities	Hotels	Sports/Physical Fitness Facilities
Bars/Restaurants/Cafeterias	Industrial Facilities	University Laboratories]

Suitable for Use as a Disinfectant and Fungicide on most hard, non-porous surfaces [(e.g., linoleum, vinyl, sealed asphalt, sealed nonporous concrete, sealed nonporous brick and stone, glazed porcelain and ceramic tile, plastic (vinyl, polyethylene, and polypropylene), and glass)]. This product is compatible with stainless steel and aluminum surfaces. If this product is intended to be used on other metal surfaces it is recommended that you apply this product to a small test area to determine compatibility before proceeding with its use. Areas of appropriate use as a disinfectant and/or fungicide include:

[Appliances	Countertops	Phones
Attics	Crutches	Railings
Banisters/Hand railings	Desks	Remote Controllers
Bathrooms/Restrooms – fixtures/appliances	Devices and equipment – non-electrical and non-critical health care related	Stairs/Steps
Benches – bench tops	Doors – handles/knobs	Seats
Bottles	Fans	Tables
Cabinets/Shelves	Faucets/Spickets	Tires
Cages	Fences/Gates/Partitions	Toys
Cans	Floors	Walls
Carts	Garbage/Trash/Refuse/Waste – cans/bins/chutes/carriers/compactors	Windows – frames/sills
Chairs/Wheelchairs	Kitchens – appliances/fixtures	Window glass
Ceilings	Light – switches/covers	Wheels]
Containers	Lockers	
Coolers	Poles/Posts	

Suitable for Use as a Disinfectant and Fungicide on most hard, non-porous surfaces in transportation applications, including:

[Ambulances/Patient transfer vehicles
Bicycles
Cars
Taxis/Buses/Subways
Trains/Planes/Ships/Boats/Cruise Ships
Trucks/Fire trucks
Other public transportation and mass transit]

Suitable for Use as a detergent cleaner on most surfaces, including:

Suitable Materials	Stains	
[Counter tops	Blood	Ice cream
Floors	Chocolate	Jellies and Jams
Table tops	Coffee	Ketchup
Vinyl tile floor	Cranberry juice	Marker
Walls	Grape juice	Pen
White boards	Grass stain	Tea
Blue jean*	Grease	Wine]
Carpet*		
Fabric*		
Khaki*		

* Will not disinfect non-porous surfaces.

{Optional Cleaning Claims include:}

[Cleaning examples include:

Removing Permanent markers such as Sharpie, Stanley Industrial Grade, Just Basics, and Bic Permanent markers off of floors, table tops and white boards.

SteriCide easily removes pen, marker, crayons marks, black heel scuff marks, grease and tar;

SteriCide removes black heel scuff marks off a vinyl tile floor;

SteriCide removes soap scum in bathtub and sink with hardly any effort;

SteriCide removes dirt from small cracks around sink drain;

SteriCide removes old/dried red children’s sun tan lotion from vinyl tile;

Also an excellent laundry presoak for a variety of known and unidentified stains –

- Tea
- Coffee
- Grape juice
- Cranberry juice
- Grass stain
- Ketchup
- Ice cream
- Chocolate
- Jellies and Jams]

To Clean [Remove Stains]:

SteriCide is an effective cleaner. Remove gross soil prior to application of SteriCide. Apply by wiping, mopping or as a coarse spray. Allow surface to remain thoroughly wet for at least 2 minutes, then wipe with a clean cloth or allow to air dry.

To Disinfect:

SteriCide is an effective broad-spectrum hospital or medical environment disinfectant against gram positive and gram-negative bacteria (i.e., *Staphylococcus aureus*, Methicillin Resistant *Staphylococcus aureus* (MRSA), *Salmonella enterica*, and *Pseudomonas aeruginosa*). Heavily soiled surfaces must be pre-cleaned prior to disinfection; remove gross soil and then wash with SteriCide followed by thorough potable water rinse. Apply this product by wiping, mopping or as a coarse spray. Allow surface to remain thoroughly wet for at least 2 minutes, then wipe with a clean cloth or allow to air dry. SteriCide may be used in general (household) commercial and medical environments to clean, disinfect, and deodorize inanimate surfaces.

To Kill Fungi:

SteriCide is an effective Fungicide against *Trichophyton mentagrophytes* and *Aspergillus niger*. Heavily soiled surfaces must be pre-cleaned prior to disinfection; remove gross soil and then wash with SteriCide followed by thorough potable water rinse. Apply this product by wiping, mopping or as a coarse spray. Allow surface to remain thoroughly wet for at least 2 minutes, then wipe with a clean cloth or allow to air dry. Reapply weekly or when mold and mildew growth reappears.

Use as a Sporicide (Sterilant) {this use will only appear on container sizes ≥ 1 quart}

SteriCide is not to be used as a sterilant on any surface or instrument that is introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body. This product is not approved for use as a sterilant on electrical and critical/semi-critical health care related devices.

As required to be a Sterilant, SteriCide has been shown to be an effective sporicide against *Bacillus subtilis* and *Clostridium sporogenes* when used as directed.

{This statement is only for use on containers < 1 gallon}

[A Sterilant* is an antimicrobial pesticide that destroys or eliminates all forms of microbial life in the inanimate environment, including bacterial spores.]

{This statement is only for use on containers ≥ 1 gallon}

[* "A Sterilizer is an antimicrobial pesticide that destroys or eliminates all forms of microbial life in the inanimate environment, including bacterial spores. The term "sporicide" is deemed to be synonymous with "sterilizer". Since sterilization includes eradication of all living microorganisms, such claims are intrinsically related to protection of human health (EPA DIS/TSS-9)."]

This product is suitable for use as a sporicide (sterilant) on most hard non-porous materials and articles. It is compatible with stainless steel, aluminum, linoleum, glazed porcelain and ceramic tile, plastic (vinyl, polyethylene, and polypropylene), and glass. [If this product is intended to be used on other metal surfaces, it is recommended that you apply this product to a small test area to determine compatibility before proceeding with its use.]

Sterilization by Flooding: Flooding application may be used in situations where a large volume can be spread over a floor or pan surface where the liquid can be contained for the entire contact time without complete evaporation. Remove gross soil from the surface to be sterilized. Use enough product to cover the surface to be treated, ensuring that the surface is covered with the product for the entire 20 minute contact time. Reapply product if it begins to dry out during the 20 minute contact time.

Sterilization by Immersion: Immersion may be used to treat immersible non-electrical articles, tools, and devices that are not related to critical/semi-critical health care [(e.g., jewelry, keys, eyewear, small containers, coins, toys, etc.)]. Remove any obvious debris or organic material from the surface or object to be sterilized. Dismantle devices prior to pre-cleaning, if necessary. Pour appropriate amount of SteriCide into a tray or receptacle that will hold the items to be treated and allow for their complete immersion in, and surface contact with, the solution. Immerse articles for a minimum of 20 minutes. Transfer the treated articles to a water rinse bath to remove the treatment solution. Dry the SteriCide treated articles prior to reassembly or use.

Note: SteriCide may cause bleaching of treated surfaces; test item if unsure. Before using SteriCide on metal surfaces other than stainless steel and aluminum, it is recommended that the product be tested on a small area to determine compatibility.

This product must not result in direct or indirect contamination of food products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Do not return SteriCide to the original container after it has been removed. Avoid all contaminants, especially dirt, reducing agents and metals. Contamination may reduce shelf life and can induce decomposition. In case of decomposition douse container with cool water and dilute with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight.

Procedure for Leaks or Spills

Stop leak if this can be done without risk. Shut off ignition sources: no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide mixture, or rinsate is in violation of Federal Law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements.

Container Disposal: Nonrefillable container. Do not reuse or refill this container.

{1 gallon or less} If empty, securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions.]

{>1 to 5 gallons} Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instruction for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[OR]

{>5 Gallons} Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Empty drums and bottles are not returnable to ConSeal unless special arrangements have been made.]

Manufactured by:
ConSeal International, Inc.
90 Kerry Place, Suite
Norwood, MA 02062

EPA Reg. No.: 58300-
EPA Est. No.: 58300-FL-1

[WARRANTY

ConSeal International Inc. warrants that this product complies with the specifications expressed on the label. To the extent consistent with applicable law, **ConSeal International Inc.** makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose.]

{The following statement and its corresponding table is optional language}

[This product has been demonstrated efficacy against the following specific organisms:]

Organism	ATCC No.	Contact Time
<i>Pseudomonas aeruginosa</i>	15442	2 minutes
<i>Salmonella enterica</i>	10708	90 seconds
<i>Staphylococcus aureus</i>	6538	90 seconds
Methicillin Resistant <i>S. aureus</i> (MRSA)	33592	90 seconds
<i>Bacillus subtilis</i>	19659	20 minutes
<i>Clostridium sporogenes</i>	3584	20 minutes
<i>Trichophyton metagrophytes</i>	9533	2 minutes
<i>Aspergillus niger</i>	16404	2 minutes

[During the 20 minute time required to sterilize a treated surface, SteriCide kills bacteria and fungi in the first 90 second to 2 minutes.]